

# STORAGE AND HANDLING

# Storage and Handling of Immunobiologics - 2011

- ❑ Storage Temperature
- ❑ Storage Units
- ❑ Temperature Monitoring
- ❑ Response to Out-of-Range Temperature Reading
- ❑ Expiration Dates and Windows
- ❑ Multidose Vials

# Storage and Handling of Immunobiologics - 2011

- ☐ Storage Temperature
- ☐ Storage Units
- ☐ Temperature Monitoring
- ☐ Response to Out-of-Range
  - ☐ Temperature Reading
- ☐ Expiration Dates and Windows
- ☐ Multidose Vials

# Storage and Handling of Immunobiologics - 2016

☐ Storage Temperature

☒ ~~Storage Units~~

[www.cdc.gov/vaccines/recs/storage/toolkit/default.htm](http://www.cdc.gov/vaccines/recs/storage/toolkit/default.htm)

☒ ~~Temperature Monitoring~~

☐ Response to Out-of-Range

☐ Temperature Reading

☒ ~~Expiration Dates and Windows~~

☒ ~~Multidose Vials~~

# Topics in Storage and Handling Toolkit

- ❑ **Best Practices which break down into:**
  - Equipment considerations for storage units and thermometers
  - Maintaining the cold chain
  - Routine storage and handling practices
  - Inventory management
  - Emergency procedures for protecting vaccine inventories

# Topics in Storage and Handling Toolkit

## ❑ Best Practices which break down into:

- Equipment considerations for storage units and thermometers
  - Stand-alone units preferred
  - Use of glycol-buffered probes
- Maintaining the cold chain
  - Required temperatures
- Routine storage and handling practices
  - Positioning of vaccine
  - Labeling trays and containers
- Inventory Management
  - Interpreting expiration dates
- Emergency procedures for protecting vaccine inventories
  - Transporting to off-site facilities

## Topics in Storage and Handling Toolkit

- ❑ Information Deleted in General Recs
- ❑ Storage and Handling Toolkit is CDC cleared, represents best practices
- ❑ Harmonized with VFC regulations described in the VFC operations manual

# Storage Temperature

- ❑ Retaining the table of temperature ranges P5
- ❑ Categories of vaccine
  - Nonlyophilized, aluminum-adjuvanted vaccines
  - Nonlyophilized non-aluminum adjuvanted vaccines
  - Lyophilized (nonvaricella) vaccines
  - Varicella-containing vaccines
  - Noninjectable vaccines



# Storage Temperature

- ❑ Retaining the table of temperature ranges P5
- ❑ Categories of vaccine
  - Nonlyophilized, aluminum-adjuvanted vaccines
    - Lose potency when exposed to freezing temperatures
  - Nonlyophilized non-aluminum adjuvanted vaccines
    - Might lose potency if exposed to freezing temperatures
  - Lyophilized (nonvaricella) vaccines
    - Do not need to be frozen (but lyophilized pellet can be with exception of MenHibrix pellet)
  - Varicella-containing vaccines
    - Must be kept frozen or vaccine virus will degrade
  - Noninjectable vaccines
    - Do not freeze

# Response to Out-of-Range Temperature Reading

- ❑ Have a plan ahead of time
- ❑ Mark vaccine “do not use”
- ❑ See if temperature deviation has a resolvable solution
  - Door left open
  - Unplugged
- ❑ Move vaccine to alternate site
- ❑ Contact state/local health department or manufacturer to determine if vaccine is viable
- ❑ If doses already administered, contact state/local health department

## Response to Out-of-Range Temperature

- ❑ As a general rule, vaccines that have been stored at inappropriate temperatures should not be administered unless public health authorities or the manufacturer determine it is safe to do so. (P3, L28)
- ❑ If such vaccines already have been administered, vaccine exposed to inappropriate temperatures that is inadvertently administered should generally be repeated. Clinicians should consult promptly with state or local health departments in these situations. Consultation with CDC is available when necessary. (P3, L31)

## Table of Storage Temperatures

- ❑ Added PRP-T Hib-MCV2 (MenHibrix)
- ❑ Added new minimum temperatures for all varicella containing vaccines (negative 58 degrees Fahrenheit, negative 50 degrees Celsius)
  - Most storage units cannot reach this temperature
  - The cutoff is emphasized because transport on dry ice can cause variations in temperature, perhaps as low as negative 58 degrees Fahrenheit
  - Lead to increased gas permeability of rubber vial – theoretically compromising sterility (especially in presence of water vapor (dry ice))

## Table of Storage Temperatures

- ❑ Removed the “Comments” column
- ❑ Most precise information on light sensitivity and degree of thermostability can be found in the FDA product information

# Vaccine Storage Temperature Recommendation Table (Page 6)

<b>Varicella-containing vaccines</b>		
MMRV†	-58°F--5°F (-50°C to -15°C)	35°F--77°F (2°C--25°C)  Can be refrigerated or stored at room temperature
Varicella†	-58°F--5°F (-50°C to -15°C)	35°F--77°F (2°C--25°C)  Can be refrigerated or stored at room temperature
Herpes zoster†	-58°F--5°F (-50°C to -15°C)	35°F--77°F (2°C--25°C)  Can be refrigerated or stored at room temperature

# Vaccine Storage Temperature Recommendation Table (Page 6)

Varicella-containing vaccines		
MMRV†	-58°F--5°F (-50°C to -15°C)	35°F--77°F (2°C--25°C)  Can be refrigerated or stored at room temperature
Varicella†	-58°F--5°F (-50°C to -15°C)	35°F--77°F (2°C--25°C)  Can be refrigerated or stored at room temperature
Herpes zoster†	-58°F--5°F (-50°C to -15°C)	35°F--77°F (2°C--25°C)  Can be refrigerated or stored at room temperature

## Updated Temperature Logs

- ❑ One for refrigerator storage, one for freezer storage
- ❑ Has spaces to log the maximum and minimum temperature of the day (per new best practice recommendations)
- ❑ Doesn't have spaces to check off a box if the temperature is out of range
  - Emphasizes the need to take immediate action if temperature is out-of-range





## Temperature Log for Refrigerator – Fahrenheit

DAYS 1–15

Month/Year \_\_\_\_\_ VFC PIN or other ID # \_\_\_\_\_ Page 1 of 3

Facility Name \_\_\_\_\_

### Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an "X" in the row that corresponds to the refrigerator's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

### Take action if temp is out of range—too warm (above 46°F) or too cold (below 35°F).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)															
Danger! Temperatures above 46°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!															
TEMPERATURES	46°F														
	45°F														
	44°F														
	43°F														
	42°F														
	41°F														
ACCEPTABLE	Aim for 40°F														
	39°F														
	38°F														
	37°F														
	36°F														
	35°F														
Danger! Temperatures below 35°F are too cold! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!															
ACTION	Write any out-of-range temps (above 46°F or below 35°F) here:														
	Room Temperature:														

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

Adapted with appreciation from California Department of Public Health

DISTRIBUTED BY THE

IMMUNIZATION ACTION COALITION 1573 Selby Avenue • St. Paul, MN 55104 • 651-647-9009 • www.immunize.org • www.vaccineinformation.org

Technical content reviewed by the Centers for Disease Control and Prevention  
www.immunize.org/cdcg.cdf/j303377.pdf • Item #P90377 (6/13)



## Temperature Log for Freezer – Fahrenheit

### DAYS 1–15

#### Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an "X" in the row that corresponds to the freezer's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Month/Year \_\_\_\_\_ VFC PIN or other ID # \_\_\_\_\_ Page 1 of 3

Facility Name \_\_\_\_\_

#### Take action if temp is out of range—too warm (above 5°F) or too cold (below -58°F).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)															
<b>Danger! Temperatures above 5°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!</b>															
5°F															
4°F															
3°F															
2°F															
1°F															
0°F															
-1°F															
-2°F															
-3°F															
-4°F															
-58°F to -5°F															
<b>ACTION</b> Write any out-of-range temps (above 5°F or below -58°F) here.															
Room Temperature															

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

DISTRIBUTED BY THE

**IMMUNIZATION ACTION COALITION**

1573 Selby Avenue • St. Paul, MN 55104 • 651-647-9009 • [www.immunize.org](http://www.immunize.org) • [www.vaccineinformation.org](http://www.vaccineinformation.org)

Adapted with appreciation from California Department of Public Health

Technical content reviewed by the Centers for Disease Control and Prevention  
[www.immunize.org/vaccineaction/vacinfo.pdf](http://www.immunize.org/vaccineaction/vacinfo.pdf) • Item #790367 (01/13)

# The General Recommendations Work Group

## ACIP Members

Jeff Duchin (Chair)  
Doug Campos-Outcalt  
Cynthia Pellegrini

## CDC Lead

Andrew Kroger

## Consultants

William Atkinson (IAC)  
Richard Clover  
Geoff Evans  
Shainoor Ismail  
Deborah Wexler (IAC)

## Liaison Representatives

Chris Barry (AAPA)  
Katie Brewer (ANA)  
Stephen Foster (APhA)  
Stanley Grogg (AOA)  
Paul Hunter (AAFP)  
Harry Keyserling (SHEA)  
Susan Lett (AIM)  
Kelly Moore (AIM)  
Walter Orenstein (AAP, NVAC)  
Mark Sawyer ( PIDS)  
Richard Zimmerman (AAFP)